

Batch Certificate For Research Use Only

PRODUCT INFORMATION AND QUALITY CONTROL

NAME OF PRODUCT	EGFR-Multiplex 0.1% AF cfDNA in Plasma
DESCRIPTION	Human proteins in common plasma concentrations, electrolytes, EDTA, cfDNA / ctDNA in common plasma concentrations
CATALOG NUMBER	SID-000014
BATCH NUMBER	00036
MANUFACTURING CONDITIONS	<ul style="list-style-type: none"> • Manufactured and sealed in class 2 safety cabinet • At room temperature
PACKAGE SIZE AND TYPE	<ul style="list-style-type: none"> • 2D barcoded tube with screw cap • Material: Polypropylen (PP)
DATE OF MANUFACTURE	08.01.2020
EXPIRY DATE	07.01.2021
CONCENTRATION	80 ng/ml (ds DNA)
QUANTITY	400 ng (ds DNA)
NOMINAL VOLUME	15.8 µl in 5 ml plasma
MUTATION	<p>p.G719S (COSM6252*, COSV51767289*, substitution, c.2155G>A, Exon 18)</p> <p>p.E746_A750delELREA (COSM6225*, COSV51765066*, deletion, c.2236_2250del15, Exon 19)</p> <p>p.S752_I759delSPKANKEI (COSM6256*, COSV51774879*, deletion, c.2254_2277del24, Exon 19)</p> <p>p.S768I (COSM6241*, COSV51768106* substitution, c.2303G>T, Exon 20)</p> <p>p.V769_D770insASV (COSM20884*, COSV51850427* Insertion, c.2303_2304insTGTGGCCAG, Exon 20)</p> <p>p.T790M (COSM6240*, COSV51765492*, substitution, c.2369C>T, Exon 20)</p> <p>p.L858R (COSM6224*, COSV51765161*, substitution, c.2573T>G, Exon 21)</p> <p>p.L861Q (COSM6213*, COSV51766344*, substitution, c.2582T>A, Exon 21)</p> <p><small>* GRCh38 COSMIC v90</small></p>
ALLELIC FREQUENCY	0.1%
QUALITY	<p>DNA quantity metrological traceable to internationally certified reference material¹</p> <p>The copy number values are metrologically traceable to the natural units count 1 and ratio 1 and International System of Units (SI) derived units of volume.</p>
STORAGE CONDITIONS	+ 2-8 °C

¹ ERM_AD442K
Phone: +49 (0) 381 377 182 01

MANUFACTURING AND QUALITY CONTROL SITES	SensID GmbH Schillingallee 68, 18057 Rostock, Germany																																	
TEST METHOD AND ACCEPTANCE CRITERIA	Quality Control	Test Method	Acceptance criteria																															
	Fragmentation	Fragment Length Analysis ² Agilent High Sensitivity DNA Kit (Agilent Technologies)	peak size 167 bp ± 10% (151 bp – 181 bp)																															
	Quantification	Total DNA measurement: Spectrophotometry ssDNA [ng/μl] = (A260- A320)*38 ^{2,3} dsDNA measurement ² : Qubit dsDNA BR Assay Kit (Invitrogen)	ssDNA: n.a. ⁴ dsDNA: n.a. ⁴																															
	Allelic Frequency	dPCR Analysis ² using BioRad QX200™ System	AF 0.1% ±60% (0.04–0.16%)																															
RESULTS OF ANALYSIS	<table border="1"> <thead> <tr> <th></th> <th>Result</th> <th>PASS/FAIL</th> </tr> </thead> <tbody> <tr> <td>Fragmentation</td> <td>173 bp</td> <td>PASS</td> </tr> <tr> <td>Quantity</td> <td>26.9 ng/μl (total DNA) 25.3 ng/μl (dsDNA)</td> <td></td> </tr> <tr> <td rowspan="8">Allelic Frequency</td> <td>Mutation</td> <td>AF in %</td> </tr> <tr> <td>L858R</td> <td>0,04</td> </tr> <tr> <td>L861Q</td> <td>0,07</td> </tr> <tr> <td>S768I</td> <td>0,05</td> </tr> <tr> <td>E746_A750delELREA</td> <td>0,07</td> </tr> <tr> <td>T790M</td> <td>0,12</td> </tr> <tr> <td>G719S</td> <td>0,07</td> </tr> <tr> <td>V769_D770insASV</td> <td>0,04</td> </tr> <tr> <td>S752_I759delSPANKEI</td> <td>0,04</td> </tr> <tr> <td></td> <td></td> <td>PASS</td> </tr> </tbody> </table>				Result	PASS/FAIL	Fragmentation	173 bp	PASS	Quantity	26.9 ng/μl (total DNA) 25.3 ng/μl (dsDNA)		Allelic Frequency	Mutation	AF in %	L858R	0,04	L861Q	0,07	S768I	0,05	E746_A750delELREA	0,07	T790M	0,12	G719S	0,07	V769_D770insASV	0,04	S752_I759delSPANKEI	0,04			PASS
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COMMENTS/REMARKS	Additional information: Copy numbers (CN) of the respective measurements <i>Table 1 indicates the values of the QC assays performed by SensID GmbH with an DNA input of ~80 ng. The value for the respective mutation results from the mean value of three measured replicates (CN values are rounded). CN concentration values per microliter (μl), are based on droplet digital (ddPCR) assay counts dilution factors, and droplet volume measurements. The detection of the amount of CNs may vary depending on the assay used.</i>																																	

² Measured before spiking in

³ Protocol NK603 – Community Reference Laboratory for GM Food and Feed

⁴ not applicable

Therefore, due to assay properties, there may be deviations in the observed number of copies and allele frequencies compared to the values given here.

Mutation	CN wt⁵/μl	CN mut⁶/μl
L858R	3491	2
L861Q	4584	6
S768I	3200	2
E746_A750delELREA	3843	3
T790M	3649	4
G719S	4130	4
V769_D770insASV	3362	1
S752_I759delSPANKEI	2337	1

Name and position/title of Person authorising the batch release:

Mr. Björn Nowack

Date of batch release: 13.01.2020

Signature batch release: Björn Nowack

This document was created electronically and is valid without a signature.

⁵ Wild Type

⁶ Mutation